

### **REMARKS**

This amendment is in response to the Official Action dated January 21, 2009. Claims 1-5 have been amended, claims 6-8 have been added, no claims have been canceled; as such, claims 1-8 are now pending in this application. Claims 1 and 5 are independent claims. Reconsideration and allowance is requested in view of the claim amendments and the following remarks. Support for the new and amended claims can be found in paragraphs [0027-0028] and [0038] of the specification.

#### **35 USC § 112, ¶2 Rejections**

Claim 4 has been rejected under 35 U.S.C. § 112, ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Specifically, Claim 4 includes the phrase “adsorption-type,” which the examiner believes renders the claims unascertainable. Examiner’s has suggested the “-type” be deleted. Applicant, in this response, has deleted the “-type” from the claim.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 4 under 35 U.S.C. § 112, ¶2 as being indefinite.

#### **35 USC § 102 Rejections**

Claims 1 and 5 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Gropper et al (US 5,540,220, hereinafter referred to as “Gropper ‘220”) or in the alternative under 35 U.S.C. § 103 (a). Applicant respectfully traverses this rejection.

Claim 1 recites: *[a]n oxygen supplying apparatus comprising an oxygen generating means, an oxygen supplying means for supplying the oxygen generated by the oxygen generating means to a user and a single automatic closing valve placed on an oxygen-supplying passage, wherein the oxygen supplying apparatus comprising:*

*a respiration sensor which detects the respiration of the user and provides a respiration signal;*

*a supply method setting means which selects the supply in a continuous flow or the supply in synchronism with the respiration of the user;*

*a flow rate setting means for a supply flow rate set value; and,*

*a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow, or opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of said single automatic closing valve corresponding to the flow rate set value, wherein said single automatic closing valve is controlled by the controlling means which had taken the information set by the supply method setting means and the flow rate setting means.*

Claim 5 as amended recites: *[a]n oxygen supplying apparatus comprising an oxygen generating means, an oxygen supplying means for supplying the oxygen generated by the oxygen generating means to a user and a single automatic closing valve placed on an oxygen-supplying passage, wherein the oxygen supplying apparatus comprising:*

*a respiration sensor which detects the respiration of the user and provides a respiration signal;*

*a supply method setting means which selects the supply in a continuous flow or the oxygen supply in synchronism with the respiration of the user;*

*a flow rate setting means for setting a supply flow rate set value; and,*

*a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply*

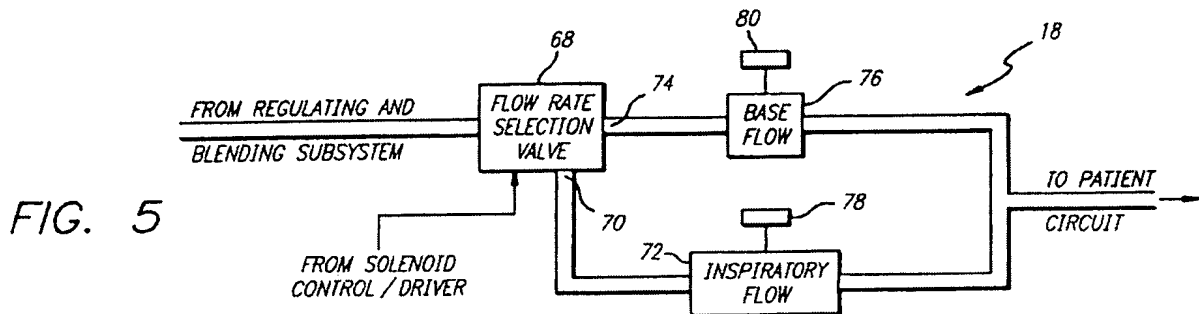
*method setting signal of the continuous flow, or opens said single automatic closing valve on the inhalation starting point based on the respiration signal of the respiration sensor by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of said single automatic closing valve corresponding to the flow rate set value, wherein the supply method setting means and the flow rate setting means are composed separately and independently.*

These claimed features are not disclosed nor suggested by Gropper '220. Gropper '220 discloses a method and apparatus for pulmonary ventilation support which represents an improvement in the mode of mechanical ventilation. It includes a pressurized gas system that supplies respiratory gas to a patient at a selected inspiratory flow rate, an exhalation valve that opens the expiratory flow path in response to the elapsing of the selected inspiratory time period, and maintains a selected proximal pressure limit during the inspiratory time period. Gropper '220 does not teach a controlling means which controls an aperture of said single automatic closing valve corresponding to the supply flow rate set value of the flow rate setting means by receiving a supply method setting signal of the continuous flow. In contrast, Gropper '220 discloses three valves, namely, a flow rate selection valve 68, a clinician-adjustable inspiratory flow valve 72 and a clinician adjusted base flow valve 76.

The Office Action alleges on page 3, second paragraph, that "*a controlling means(46) that controls the aperture of an automatic closing valve(68) corresponding to the supply flow rate set value by receiving a supply method setting signal of the continuous flow, or opens the automatic closing valve on the inhalation starting point based on the respiration signal by receiving a supply method setting signal of the synchronous flow and at the same time controls the open time of the automatic closing valve corresponding to the flow rate set value, wherein the closing val[v]e is controlled by the controlling means which had taken the information set by the supply method (assist trigger signal) and the flow rate setting means,*" can be found in column 8, lines 40 – 60 and column 17, lines 5 – 31. This is inaccurate.

Column 8, lines 37 – 55, of Gropper '220 illustrates the components and function of the flow control subsystem 18 (see FIG 5 reproduced below). Gas from the regulating and blending

subsystem 16 is received in the inlet of a solenoid-actuated flow rate selection valve 68. The flow rate selection valve 68 has two outlets: a first outlet 70 communicates with the inlet of a clinician-adjustable inspiratory flow valve 72, and a second outlet 74 communicates with the inlet of a clinician-adjustable base flow valve 76. Either the first or second outlet of the flow rate selection valve 68 is opened in response to a first solenoid actuation signal generated by the solenoid control/driver circuit 66. The first solenoid actuation signal actuates the flow rate selection valve 68 so as to open its first outlet during inspiratory phase and its second outlet during expiratory phase. In other words, Gropper '220 discloses and clinician-adjusted inspiratory flow valve 72 and a clinician-adjusted base flow valve 76 in addition to flow rate selection valve 68.



Column 17, lines 5 – 31, of Gropper '220 discloses the controlling valves dependent on “assist disabled” period. It is stated that if the ventilator is not in the assist disabled period, an algorithm determines if the assist trigger “window” is open; that is, if the ventilator’s operational mode would permit the ventilator to provide machine-assisted breath, that, if the window is open, the assist trigger module 98 of Fig. 4 generates an assist trigger output signal that is inputted to the breath control module 56, that the breath control module 56, in turn, responds by sending a control signal having the first (inspiration initiation) value to the solenoid control driver circuit 66, which, in turn, responds by generating first and second solenoid actuation signals, and that, as a result, the first and second solenoid actuation signals actuate the flow rate selection valve [68] to select the inspiratory flow rate, and the reference pressure selection valve 94 [of pressure reference subsystem 36 (see Fig. 6)] to select the PIP reference pressure.

Again there is no mention of controlling the aperture of a single automatic closing valve corresponding to the supply flow rate set valve of the flow rate setting means. Gropper '220 simply discloses a means for controlling the actuation of the first and second solenoid in which the inspiratory phase is terminated either by the elapsing of the pre-selected inspiratory time period, or by the reaching of the pre-selected tidal volume.

As such, Gropper '220 therefore fails to teach or suggest various features of independent claim 1. Furthermore, at least for the reason disclosed above, claims 5-8 are not disclosed by Gropper '220 because they depend on independent claims 1.

Accordingly, Applicant respectfully requests that the rejection of the claims under 35 U.S.C. § 102(b) as being anticipated by Gropper '220 be withdrawn and under 35 U.S.C. § 103(a) as being unpatentable over Gropper '220 be withdrawn.

### **35 USC 103 Rejections**

Claims 2-4 have been rejected under 35 U.S.C. § 103 as being unpatentable over Gropper '220 alone. Applicant respectfully traverses this rejection.

Claims 2-4 depend from and thus incorporate the features of claims 1, which are neither disclosed nor suggested by Gropper '220, for the reasons stated above.

Regarding claim 2, Applicant respectfully submits that there is no *motivation for* or *suggestion of* modifying the diameter of the automatic closing valve (45) of Gropper '220 to have "a response time from a full close state to a full open state of 0.1 sec or less." Applicant notes that even when obviousness is based on a single prior art reference, there must be a showing of suggestion or motivation to modify the teachings of that reference. The Office Action admits Gropper '220 is silent regarding the automatic closing valve to have "a response time from a full close state to a full open state of 0.1 sec or less."

Obviousness is a question of law based upon several factual inquiries, namely, the scope and content of the prior art, the difference between the prior art and the claims, and the level of ordinary skill. (*See Graham et al. v. John Deere Company et. al.*, 383 U.S. 1, 148 USPQ 459; *See also Examination Guidelines for Determining Obviousness*, MPEP § 2141.II.C 1).

These *Graham* inquiries are required by *KSR*, and their omission is a failure to establish a *prima facie* case of obviousness. (*KSR*, 127 U.S. at 1734, 82 USPQ2d at 1391; *See Graham et al. v. John Deere Company et. al.*, 383 U.S. 1, 148 USPQ 459; *See also Examination Guidelines for Determining Obviousness*, MPEP § 2141.II.C 1).

Moreover, all of the claim limitations must be taught or suggested by the prior art in order to establish *prima facie* obviousness of a claimed invention. (*In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP § 2143.03; *accord*, M.P.E.P. § 706.02(j)).

Effectively, "[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (*See KSR*, 127 U.S. at 1341, 82 USPQ2d at 1396 citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

The goal of examination is to clearly articulate any rejection, which under *Graham* and *KSR* is done through a comparison between the prior art and the claims at issue. (*see* MPEP §§ 706, Rejection of Claims; *see also Graham et al. v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966)).

Consequently, the U.S. Patent and Trademark Office has the initial burden of demonstrating through appropriate reasoning that all the claimed features of the invention are taught by the prior art. (*In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988)).

The Office Action fails to detail "the scope and content of the prior art." (*KSR*, 127 U.S. at 1734, 82 USPQ2d at 1391; *See Graham et al. v. John Deere Company et. al.*, 383 U.S. 1, 148 USPQ 459). Without "the scope and content of the prior art," Applicant can not identify the root of

the Office Action's rejections. (*Id.*). Consequently, the Office Action's omission (of this required factor) is a failure to establish a *prima facie* case.

The Office Action lacks sufficient or explicit reasoning for its rejection of independent claim 1. Without explicit reasoning, the Office Action is concluding that the combinations of prior art are obvious simply because the prior art exists; therefore, these rejections are conclusory statements for lack of a comparison, clarity, and reasoning. Again, conclusory statements with no explicit reasoning are insufficient to establish a *prima facie* case.

Also, the Office Action fails to detail "the level of ordinary skill." (*KSR*, 127 U.S. at 1734, 82 USPQ2d at 1391; *See Graham et al. v. John Deere Company et. al.*, 383 U.S. 1, 148 USPQ 459; *See also Examination Guidelines for Determining Obviousness*, MPEP § 2141.II.C ¶¶ 1). The Office Action refers to "one skilled in the art" but does not define the field (art) nor the level of expertise required (skill). The prior Non-Final Office Action of August 4, 2008, failed to detail this factor and the current Office Action repeats this omission. Again, an omission of this required factor is a failure to establish a *prima facie* case.

The relied upon reference would still fail to yield the claimed invention, Applicant submits that a *prima facie* case of obviousness for claim 1 has not been presented. Applicant also notes that the offered combination appears to be a failed attempt to reconstruct the claimed invention in hindsight.

Furthermore, at least for the reason disclosed above, claims 2-4 overcome Gropper '220 because they depend on independent claim 1. Accordingly, Applicant respectfully requests that the rejection of and claims 2-4 under 35 U.S.C. § 103(a) as being unpatentable over Gropper '220 be withdrawn.

### **Double Patenting Rejection**

Claims 1-5 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, and 7 of co-pending Application No.

10/569,463. Applicant does not concede the propriety of these grounds of rejection, and asks that the requirement for a terminal disclaimer be held in abeyance pending the indication of allowable subject matter, so that Applicant can give an assessment at that time of the differences between what is claimed and allowed herein vis-à-vis the '463 application.

### **Conclusion**

In view of the foregoing arguments, all claims are believed to be in condition for allowance. If any further issues remain, the Examiner is invited to telephone the undersigned to resolve them.

This response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments supporting the patentability of their claims, including the separate patentability of the dependent claims not explicitly addressed herein, in future papers. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicant expressly does not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

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Respectfully submitted,

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